NDA 20-626/S-003

Glaxo Wellcome
Attention: Judith Babo
Project Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Babo:

Please refer to your supplemental new drug application dated August 27, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imitrex (sumatriptan) Nasal Spray.

This "Changes Being Effected" supplemental new drug application provides for labeling changes to comply with the guidance document for Industry regarding content and format for geriatric labeling. The specific changes are as follows:

1. The addition of a reference to the PRECAUTIONS-Geriatric Use section of labeling under the CLINICAL PHARMACOLOGY-Special Populations-Age section.
2. The change of the section name from PRECAUTIONS-Use in Elderly to PRECAUTIONS-Geriatric Use, and the revision of this section to incorporate updated labeling.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted August 27, 1999/Label Code RL-651), which incorporates all of the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

Labeling changes of the kind which you have proposed under the above supplemental application are permitted by section 314.70(c) of the regulations to be instituted prior to approval of the supplement. It is understood that the changes, described in the above NDA supplement, have been made.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Lana Chen, R.Ph., Regulatory Project Manager, at (301) 594-2850.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research